

**Questions and Answers for Applicants who are Submitting Applications using the ASSIST Application “Package” in Response to [PAR-13-321](#).**

**Q1: How many paper copies of my application should I submit, and should I send them to CSR and NCI or just CSR?**

A1: Do not send any paper copies to NIH, NCI, or CSR. Your application must now be submitted electronically.

**Q2: Must I apply electronically?**

A2: Yes. Apply electronically for all investigator-initiated P01 applications (for more information, go to [http://grants.nih.gov/grants/ElectronicReceipt/files/Timeline\\_NIH\\_Complex\\_Transition.pdf](http://grants.nih.gov/grants/ElectronicReceipt/files/Timeline_NIH_Complex_Transition.pdf)).

**Q3: Where is the electronic application form?**

A3: You submit applications through [ASSIST](#); see the “button” that links applicants to the ASSIST application package on the first page of [PAR-13-321](#). P01s don't involve use of a Grants.gov electronic application package.

**Q4: How do I use ASSIST?**

A4: For instructions, go to NIH's [ASSIST](#) portal and read the application and user guides. If you haven't already done so, view the videocast of a webinar about [ASSIST](#) that was held on August 13, 2013, at [http://grants.nih.gov/grants/webinar\\_docs/webinar\\_20130813.htm](http://grants.nih.gov/grants/webinar_docs/webinar_20130813.htm).

**Q5: In [PAR-13-321](#), no instructions are given about a Project Abstract/Summary and Project Narrative for the Overall component, yet they appear to be required in the associated ASSIST application package. What are the instructions?**

A5: You should upload a Project Abstract/Summary (data item #7) and a Project Narrative (data item #8) under the tab Other Project Information in the Overall Component. The abstract of the overall application should summarize the overall goals of the program as a whole, including why the integrated program is expected to have a greater impact than the individual components.

**Q6: Can the public health relevance statement for a Project be the same as that for the Overall (program project)?**

A6: The public health relevance statement should be tailored to the project, but may be the same as for the program as a whole.

**Q7: Should I describe the project-core interactions as a flow chart or in a detailed paragraph?**

A7: You may describe project-core interactions in the best way to meet the needs of your program. The more information you provide the better, since reviewers will use this in assessing the feasibility of proposed cores. When including images and/or figures, check your application image in your Commons account after its successful submission to confirm that they look right.

**Q8: In the Project Abstract/Summary for an individual research Project, should I address the interactions among other Projects and Cores in addition to including the Project's scientific description?**

A8: You may wish to briefly describe the relationships among projects and cores and their respective personnel in the project summary to show additive and synergistic interactions, possibilities, and effects. You should also describe interactions in the Research Plan for each project and in the Overall section of your application, but this should be presented in most detail in the Program Integration Component.

**Q9: Should I prepare a detailed budget, and where does it go?**

A9: You will need to prepare a detailed budget for each Project and each Core. Budgets are also required for each consortium (subcontract) project if they are part of any projects or cores. With regard to a budget (or no budget) request for Program Integration and Management, see Q25/A25 and Q26/A26 below. The only budget information included in the Overall component is the Estimated Project Funding section of the SF424 (R&R) Cover. A budget summary in the Overall section of the assembled application image in eRA Commons compiled from detailed budget data collected in the other components will be generated upon submission.

**Q10: If we are preparing a P01 application in which one Core is using either animals or human subjects to generate cell lines that will be used by multiple projects, which sections on the face page should be "Yes" for Vertebrate Animals or Human Subjects?**

A10: Each project and core using either human subjects and/or vertebrate animals needs a Human Subjects (item 5) and/or Vertebrate Animals (item 8) section under the Research Plan tab, respectively, unless the project and/or core is using cell lines only. Under the Other Project

Information tab for any Project and/or Core, indicate “Yes” or “No” for human subjects and/or “Yes” or “No” for vertebrate animals, as appropriate. If the Projects and/or Cores involve human subjects and/or vertebrate animals in research, the Overall component does not also need a Human Subjects and/or Vertebrate Animals section(s) under the Research Plan, but “Yes” should be indicated for Human Subjects and/or “Vertebrate Animals” under the Other Project Information tab. Similarly, the Administrative Core (if proposed) does not need a Human Subjects or Vertebrate Animals section. Basically, any component of the application that involves humans in research must have a Protections of Human Subjects section and any component of the application that uses animals must have a Vertebrate Animals section. These are scorable aspects of the application.

**Q11: Where should I put the biosketches?**

A11: Overall component: Include only the PD/PI and any multi-PD/PI for the entire application. A summary of Senior/Key Persons followed by their Biographical Sketches in the Overall Section of the assembled application image in eRA Commons will be generated upon submission. Under the R&R Senior/Key Person Profile for Program Integration and Management, Projects, and Cores: Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. The Biosketch can be included in any one component, i.e., only one biosketch per person is allowed in the entire application.

**Q12: Should biosketches include research support? What about other support?**

A12: Biosketches should include research support. PAR-13-321 does not ask for Other Support at time of submission; this information is typically part of the Just-in-Time (JIT) information that would only be required when an award is being negotiated.

**Q13: Does the Overall component need to include a Resources section in addition to the ones written for individual projects and cores?**

A13: Overall Program Environment and Resources should be addressed in item “10. Facilities and Other Resources” under the tab entitled “Other Project Information” -- it should contain a description of the features of the environment that will contribute to the success of the program as a whole. This information should not, however, simply be a repetition of the information provided about Resources in the other components of the application. Essential resource information should be provided in the individual Projects and Cores of the application. Resources should be addressed in detail for each Project and each Core in item “10. Facilities and Other Resources” under the tab entitled “Other Project Information.” Separately (but

tangentially related), a Resource Sharing Plan should be provided as the last subsection under the Research Plan tab for each Project and Core.

**Q14: In [PAR-13-321](#), it is stated that any of the leaders of the individual projects or cores of the P01 can serve as an additional PD/PI (Co-PD/PI) of the overall P01. Does the Co- PD/PI of the overall P01 have to be the PI of any of the individual projects or cores?**

A14: The PD/PI or one of the PDs/PIs of a P01 application does not have to be the Leader of any Project or the Director of any Core. Obviously though, the applicants should present a strong case in the application to the peer reviewers about the critical leadership roles and responsibilities that the person in question would have as a PD/PI of the program project and how s/he would fulfill them successfully.

**Q15: Should information about a program advisory committee be presented in the application?**

A15: It depends. For a new application, if advisory members have been selected and participated in evaluating the application prior to submission, then yes, you should provide their information. If you have individuals in mind but the committee has not yet been assembled or met, then there is no need to list their names. For a renewal application, you must provide names of your current program advisory committee members (since they cannot serve as reviewers for your application) as well as a description of their expertise and responsibilities.

**Q16: Are publications to be listed only once in the Overall section of the application?**

A16: No, relevant publications should be listed at the end of each component (i.e., as attachments at the end of Overall, Program Integration and Management [optional], each Project, and each Core).

**Q17: Are cited publications considered part of the Research Strategy 12-page limit?**

A17: No. Publications are separate from the Research Strategy and do not count against the 12-page limit.

**Q18: Where do letters of support belong? Are they being entered in the Overall component or do they go into each Project component or Core component?**

A18: Letters of support can be provided as attachments to Item 12. Letters of Support under the tab Research Plan for each component (i.e., for Overall, each Project, and each Core).

**Q19: Paper P01 applications required two tables: “Table of Distribution of Professional Effort in the Program” and “Table of Percentage Distribution of Shared Resource Core Effort to Projects.” Are these table required for electronic submission? If so, where do they go?**

A19: Yes, they should be included as attachments to Item 12. Other Attachments under the tab Other Project Information in the Overall component.

**Q20: The instructions for Core components in [PAR-13-321](#) state to “Provide abstract/summary of the proposed Core” in the Project Narrative slot. Is this the same document also uploaded to the Project Summary/Abstract slot? In the ASSIST application package, both documents appear to be required.**

A20: Under the tab Other Project Information for both Projects and Cores, a Project Abstract/Summary must be uploaded to data item #7 and a Project Narrative must be uploaded to item #8. (The guidance in the FOA is incorrect.)

**Q21: Is the Research Strategy page limit for ALL components 12 pages?**

A21: No. Please refer to the FOA under Page Limitations for specific limitations for each component of the application.

**Q22: The Program Integration and Management component is set up just like a project or core. Most of these items under the tab Other Project Information do not seem to be relevant to this component. How should they be handled?**

A22: Answer all of the items that require answers (i.e., those with asterisks).

**Q23: Both the Project Summary/Abstract and the Project Narrative are required (\*) for the Program Integration and Management component in the ASSIST application package, but the FOA explicitly says not to include them. We know the FOA is supposed to take precedence, but this is difficult to do when ASSIST denotes it as required. May we omit these from the PIM portion of the submission?**

A23: No, you cannot totally “omit” those sections as the ASSIST application package for PAR-13-321 requires those items to be uploaded. We suggest that you satisfy the technical requirement by simply typing and uploading the statement “Not applicable.”

**Q24: Under the Research Plan tab of the Program Integration and Management component, the only required (\*) element is the Research Strategy. Do we have to upload data to the other items?**

A24: You only need to upload the required Research Strategy (6 pages). You can ignore the items that are not required and not upload anything up to them.

**Q25: Must a budget be requested for Program Integration and Management?**

A25: If your applicant team does not need and/or want to have an actual budget for Program Integration and Management (which is fine), you will need to enter some effort but not necessarily salary for at least the PD/PI or the Contact PD/PI (if multiple PDs/PIs) in order to upload this part of the application. A “budget” (in the placeholder amount) of \$1 may (or may not) be added.

**Q26: How should the budget justification requirement be handled for the Program Integration and Management component?**

A26: If a real budget is needed and requested, provide a budget justification. If a \$1 placeholder request is uploaded, provide a budget justification stating that the costs of dealing with program integration and management are subsumed into the budgets of the other components (and are not/cannot be usefully separated from them) and that the \$1 is just a symbolic cost.

**Q27: It is still true that individual projects in a P01 can each only have one Project Leader and that individual cores in a P01 can only have one Core Director? What should be the role given to an additional faculty member who is a significant contributor to a project or core?**

A27: Individual projects and cores in a P01 can each have only one Project Leader or Core Director, respectively. Other significant contributors are listed as Co-Investigators, and those with minor roles are listed as Collaborators.

**Q28: Is there a limit on the number of letters of support that can be included in a P01 application?**

A28: There is no limit. Letters of support can be attached to any of the individual components of the application. However, letters of support should be limited to what is appropriate and justified (considering especially what the peer reviewers might find to be useful). Even when a letter of support is attached to a specific project or core, the relevance of the support to that specific project or core should be clearly stated in the letter.

**Q29: If I change some of the Projects in my P01, is my submission a renewal (and/or resubmission) or a new grant application?**

A29: It depends on your changes. A new application is expected to be substantially different in content and scope with more significant differences than are normally encountered in a resubmitted application (see [NOT-OD-10-080](https://public.csr.nih.gov/NOT-OD-10-080) and <http://public.csr.nih.gov/ApplicantResources/ReceiptReferral/Pages/Evaluation-of-Unallowable->

[Resubmission-and-Overlapping-Applications.aspx](#)). Contact your program officer to discuss your changes and their impact(s) on your program.

**Q30: Can I include a video clip or movie in my application?**

A30: For information about including video clips or movies with your application, see [NOT-OD-13-030](#). Please also check with the responsible NCI Program Officer and assigned Scientific Review Officer.